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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,206	02/09/2001	Michael Fritz	RDID0028US	5556

48801 7590 06/27/2008

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
06/27/2008	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL FRITZ, VOLKER GERSTLE,
HERBERT HARTTIG, JUERGEN SCHWAB,
JOACHIM STEINBISS, and ANDREAS RAUSCHER

Appeal 2008-0302
Application 09/780,206
Technology Center 1600

Decided: June 27, 2008

Before DONALD E. ADAMS, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 36-41, 68-73, and 76-79, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to an apparatus for detecting nucleic acids in a sample (claims 36-41, 69-71, and 77-79); an apparatus for amplifying nucleic acids (claim 68); and an apparatus for detecting nucleic acids in a liquid sample (claims 72, 73, and 76). Claims 36, 38, 40, 68, and 72 are illustrative:

36. An apparatus for detecting nucleic acids in a sample, comprising:

(a) a binding space for purifying the nucleic acids by immobilizing the nucleic acids and separating impurities,

(b) an amplification space for amplifying the nucleic acids wherein at least a part of the amplification space is identical to a part of the binding space, and

(c) a detection space for detecting the nucleic acids.

38. The apparatus of claim 36, wherein the detection space comprises a part of at least one of the amplification space and the binding space.

40. The apparatus of claim 39, wherein the capillary space is a capillary reaction vessel surrounded by a heatable metal layer.

68. An apparatus for amplifying nucleic acids comprising a capillary reaction vessel surrounded by a single heatable metal layer wherein the layer is coated on the capillary reaction vessel.

72. An apparatus for detecting nucleic acids in a liquid sample, comprising:

(a) a space comprising a capillary reaction vessel surrounded by a heatable metal layer, wherein the interior surface of the vessel binds nucleic acids;

(b) reagents for amplifying and detecting the nucleic acids that become bound to the surface;

(c) a sample transport mechanism which transports the sample and reagents through the space.

The Examiner relies on the following prior art references to show unpatentability:

Zanzucchi	US 5,593,838	Jan. 14, 1997
Yasuda	US 6,093,370	Jul. 25, 2000
Andresen	US 6,126,804	Oct. 3, 2000
Fields	US 2003/0027203 A1	Feb. 6, 2003

The rejections as presented by the Examiner are as follows:

1. Claims 36-41, 69-73, and 76-79 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Zanzucchi.

2. Claims 36-41, 68-73, and 76-79 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Yasuda.

3. Claims 68 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Andresen.

4. Claims 36-38 and 69-73 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Fields.

We reverse.

FINDINGS OF FACT (FF)

1. Zanzucchi teaches an apparatus to detect nucleic acid in a sample (Zanzucchi 2: 21-43; 4: 15-62 and Fig. 2; Ans. 4).

2. Zanzucchi's apparatus comprises, *inter alia*, "one or more capillary tubes . . . containing a sample" (Zanzucchi 4: 18-20; *see generally* Ans. 5).

3. Zanzucchi's apparatus comprises a well, wherein whole blood is filtered and lysed to isolate nucleic acid (Zanzucchi 4: 35-40; *see generally* Ans. 4). In this regard, Zanzucchi teaches that this well is preloaded or post loaded with a Leukosorb™ media which is a blood affinity binding material (Zanzucchi 9: 15-17).

4. Zanzucchi teaches that once the nucleic acid is isolated and purified the nucleic acid is moved from the isolation and purification space through a connecting channel to an amplification space wherein the nucleic acid is separated into single strands and amplified (Zanzucchi 4: 42-44; Ans. 4).

5. Zanzucchi teaches the use of a layer of paramagnetic beads in the amplification well "to bind with the DNA material moved into the well" (Zanzucchi 10: 9-10; *see generally* Ans. 5).

6. Zanzucchi teaches that after amplification the nucleic acid is moved through a connecting channel from the amplification space to a detection space wherein the nucleic acid "is assayed by known probe hybridization techniques" (Zanzucchi 4: 44-48; *see generally* Ans. 4).

7. Zanzucchi teaches that the "paramagnetic beads . . . are deposited in the second well [(the amplification well)] . . . of the present module . . . to bind DNA material and to move the DNA to the succeeding wells for amplification, detection and assay" (Zanzucchi 8: 28-31).

8. Zanzucchi's apparatus comprises "a connecting channel . . . that connects all of the wells into a single module" (Zanzucchi 4: 40-42; *see generally* Ans. 4).

9. Zanzucchi teaches a first and second well that are heated (Zanzucchi 15: 15-16). Zanzucchi teaches that the first well is heated through the use of a "layer of tin oxide **57** . . . deposited in the well **36** by CVD. A bilayer film

59 is deposited over the tin oxide film **57** in the well **36**, and a metal connection **60** is deposited along a sidewall of the well" (Zanzucchi 9: 4-10). For clarity, we reproduce Zanzucchi's FIG. 4B below:

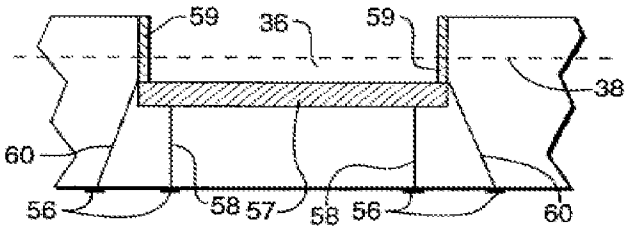


FIG. 4B

"FIG. 4B is a cross sectional view of another well embodiment of a microlaboratory disc of the invention" (Zanzucchi 3: 11-12).

10. Yasuda teaches "a method for selectively extracting a target polynucleotide having a specific base sequence from a polynucleotide mixture sample having a plurality of different sequences or from cells, and an apparatus therefore" (Yasuda 1: 4-8; *see generally* Ans. 5).

11. Yasuda's apparatus comprises a separation cell which has a solution chamber, an upper, and lower cell plate, wherein a substrate on which probes are immobilized is mounted on the lower cell plate (Yasuda 9: 17-20; *see generally* Ans. 6). For clarity, we reproduce Yasuda's FIGs. 6 and 7 below:

FIG. 6

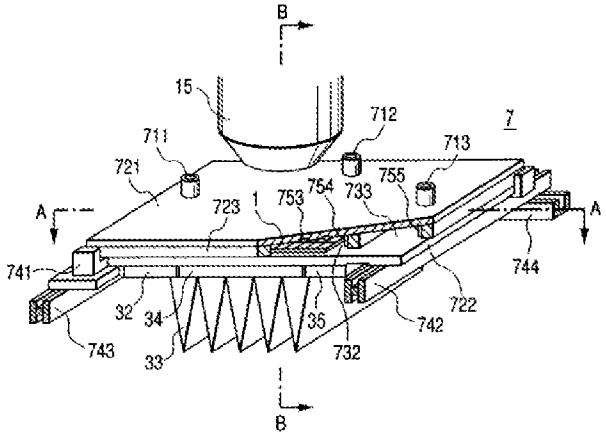
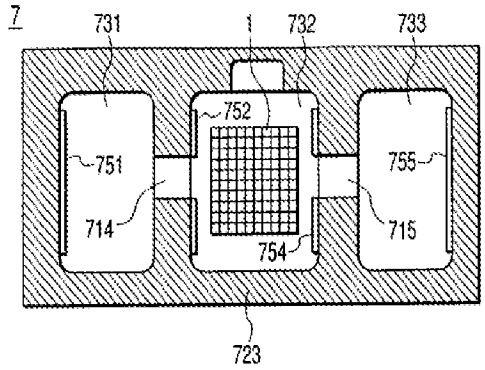


FIG. 7



"FIG. 6 is a schematic diagram illustrating a practical configuration of a polynucleotide separation cell according to the first embodiment; Fig. 7 is a sectional view along with lines A-A of the cell illustrated in FIG. 6" (Yasuda 2: 53-56).

Yasuda teaches that the "polynucleotide separation cell **7** is provided with upper cell plate **721**, lower cell plate **722**, and three sample solution chambers **731**, **732** and **733** which are partitioned by a plurality of spacers **723**" (Yasuda 9: 9-12). Yasuda teaches that the three "sample solution chambers can import and export a sample solution through sample solution inlets 711, 712 and 713 respectively" (Yasuda 9: 13-16). Yasuda teaches that probes are immobilized on substrate **1** (Yasuda 9: 18-19). Yasuda teaches that in operation

> a sample solution containing polynucleotides introduced into the sample solution chamber **731** is subject to PCR amplification . . . . polynucleotides in the sample solution in the sample solution chamber **731** are induced to the sample solution chamber **732** by setting the electrodes **751** and **755** as cathodes and the electrode **754** and the electrode above the substrate **1** as anodes. The sample solution in the sample solution chamber **732** is then heated to 95° C . . . to diassociated hydrogen bonds in polynucleotides in the sample solution to form single stranded-polynucleotides. The single stranded-polynucleotides are then hybridized to probes in the target polynucleotide hybridization area on the substrate 1 by cooling the solution to a temperature of 37° C.

(Yasuda 9: 43 – 10: 4.)

12. Yasuda teaches that the inside of the capillary wall is coated with an inner coat composed of Cr or other metal (Yasuda 16: 31-32).

13. Andresen teaches an apparatus comprising "at least one well for polymerase chain reactions located adjacent one end of . . . [a] capillary

column" (Andresen 7: 39-41). Andresen teaches that surfaces forming the wells and the "end sections of said capillary column" are coated with an electrically conductive material (Andresen 7: 57-60). Andresen teaches that this electrically conductive material may be Pt/Pd, Ag, or Sn (Andresen 5: 58-59). Andresen teaches that the apparatus may include a "means for covering the capillary column and the wells" (Andresen 7: 53-54). In this regard Andresen teaches that a cover plate may be attached after the wells are filled or loaded "with the desired reagents and buffers, or the wells can be filled through the openings and the openings filled with mineral oil to keep evaporation of the aqueous media to a minimum" (Andresen 5: 59-65).

DISCUSSION

1. Claims 36-41, 69-73, and 76-79 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Zanzucchi.

Claim 36:

According to Appellants instead of teaching the binding of nucleic acids to separate impurities as presently claimed, Zanzucchi "teaches the use of Leukosorb™ media to filter blood cells from the sample in [the] first well" (App. Br. 4). We agree with Appellants that immobilizing cells on Leukosorb™ media for isolation and lysing is not the same as immobilizing nucleic acid (FF 3). In this regard, the Examiner failed to demonstrate that a well containing Leukosorb™ is structurally the same as, or is capable of performing the same function as a binding space that comprises a structure for directly immobilizing nucleic acid as we have interpreted the claim.

At best, Zanzucchi teaches the use of a reagent, that is, a layer of paramagnetic beads in the amplification well, "to bind with the DNA material moved into the well" (FF 5). According to Zanzucchi, "paramagnetic beads . . . are deposited in the second well [(the amplification well)] . . . of the present module . . . to bind DNA material and to move the DNA to the succeeding wells for amplification, detection and assay" (FF 7). Thus, instead of a "space" wherein nucleic acid is bound Zanzucchi teach a reagent – paramagnetic beads – that bind the nucleic acid to transport the nucleic acid to each successive well. In sum, Zanzucchi does not teach a binding space, wherein at least a part of the binding space is identical to the amplification space, nor a structure for directly immobilizing nucleic acid, as required by independent claim 36. Claims 37-41, 69-71, and 77-79 depend directly or indirectly on claim 36.

Accordingly, we reverse the rejection of claims 36-41, 69-71, and 77-79 under 35 U.S.C. § 102(b) as being anticipated by Zanzucchi.

Claim 72:

Appellants assert that Zanzucchi fails to teach a reaction vessel surrounded by a heatable metal layer as required by Appellants' claim 72, part (a). We are not persuaded by the Examiner's unsupported assertion that Zanzucchi teaches "a heatable metal layer (glass layer) surrounding the wells and channels" (Ans. 11). The Examiner failed to identify any evidence on this record to support this position. Claim 72 requires the capillary reaction vessel to be surrounded by a heatable metal layer. The Examiner does not identify, and we do not find a teaching in Zanzucchi of a reaction vessel surrounded by a heatable metal layer. In our opinion,

Zanzucchi's disclosure of a tin oxide film (57) on the bottom of the well that is coated with a bilayer film (59) as illustrated in FIG. 4B (FF 9) is not sufficient to meet the requirements of Appellants' claim 72 because it does not surround the vessel, but rather lines in and along a sidewall of the well (*id.*). Claims 73 and 76 depend from claim 72.

Accordingly, we reverse the rejection of claim 72, 73, and 76 under 35 U.S.C. § 102(b) as being anticipated by Zanzucchi.

2. Claims 36-41, 68-73, and 76-79 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Yasuda.

Claim 36:

Appellants assert that Yasuda does not teach a binding space that comprises at least a part of the amplification space as recited in claim 36 (App. Br. 8). To the contrary, Appellants assert that Yasuda "teaches three separate 'sample solution chambers' (*e.g.*, Fig. 7, items 731, 732 and 733), which are partitioned by a plurality of spacers (723). Sample solution is transferred between the chambers through the communication holes (714 and 715)" (*id.* (emphasis removed)).

Yasuda teaches an apparatus, wherein amplification and hybridization/immobilizing are performed in separate spaces (e.g., FIG. 7 solution chambers **731** and **732** respectively) (FF 11). Accordingly, we disagree with the Examiner's assertion that Yasuda teaches an apparatus "wherein at least a part of the amplification space is identical to a part of an amplification space" as is required by claim 36 (Ans. 6). In sum, the Examiner has failed to identify, and we do not find, a teaching in Yasuda of

an apparatus that meets this requirement in claim 36. Claims 37-41, 69-71, and 77-79 depend, directly or indirectly, from claim 36.

For the foregoing reasons, we reverse the rejection of claims 36-41, 69-71, and 77-79 under 35 U.S.C. § 102(e) as being anticipated by Yasuda.

Claim 68:

The Examiner finds that Yasuda teaches "an apparatus comprising [a] capillary reaction vessel surrounded by a single heatable metal layer wherein the layer is coated on the capillary reaction vessel (see col. 16, 29-48, Fig. 20, 21, indicating a capillary tube coated with a metal layer, col. 23, line[s] 11-34)" (Ans. 6).

We are not persuaded that a coating on the inside of a capillary wall, as taught by Yasuda (FF 12), reads on a capillary reaction vessel surrounded by a single heatable metal layer as is required by claim 68. We find nothing in column 23, lines 11-34 to make up for this deficiency in Yasuda's teaching. Accordingly, we agree with Appellants' that Yasuda "does not teach such an embodiment" (App. Br. 11).

For the foregoing reasons we reverse the rejection of claim 68 under 35 U.S.C. § 102(e) as being anticipated by Yasuda.

Claim 72:

Claim 72 is drawn to an apparatus comprising, *inter alia*, a capillary reaction vessel surrounded by a heatable metal layer. For the reasons set forth above, with regard to claim 68, the Examiner failed to establish that Yasuda teaches a capillary reaction vessel surrounded by a heatable metal layer. Claims 73 and 76 depend from claim 72.

Accordingly, we reverse the rejection of claim 72 under 35 U.S.C. § 102(e) as being anticipated by Yasuda.

3. Claim 68 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Andresen.

Claim 68 is drawn to an apparatus for amplifying nucleic acids comprising a capillary reaction vessel *surrounded by a single heatable metal layer*. The Examiner finds that Andresen teaches an apparatus "comprising a capillary reaction vessel (see col. 7, line[s] 30-67, col. 8, line[s] 1-4) surrounded by a single heatable metal layer" (Ans. 7). According to the Examiner, Andresen teaches "that the capillary vessel is made up of a metal (glass) that is heatable layer that does teach a metal layer surrounding the capillary space and said capillary and cover plate are made up of the heatable metal layer, that is, made up of glass." (Ans. 11).

As Appellants point out, Andresen does not teach a metal layer "applied to the cover plate . . . which covers the well and the column" (App. Br. 14). Therefore, Appellants conclude that "[b]ecause the metal layer of Andresen is not applied to the cover plate, the layer does not 'surround' a capillary reaction vessel as presently recited in claim 68" (*id.*). We agree (*see* FF 13).

We are not persuaded by the Examiner's intimation that "glass" reads on a single heatable metal layer that is coated on the capillary reaction vessel (Ans. 11).

For the foregoing reasons, we reverse the rejection of claim 68 under 35 U.S.C. § 102(e) as being anticipated by Andresen.

4. Claims 36-38 and 69-73 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Fields.

Claim 36:

According to the Examiner, Fields three-way connecting valves unite all . . . three spaces [(binding space, amplification space, and detection space)] and thus the limitation that 'at least part of the space' does read on the instant claims" (Ans. 12; 8). However, as Appellants explain,

> Fields teaches an apparatus where nucleic acids are liberated in [an] incubation chamber . . . . The lysate solution containing the nucleic acids is transferred to and passed through the target molecule absorption filter . . . to which the nucleic acids bind . . . . The nucleic acids are washed from the filter and transferred to [a] device . . . for PCR amplification . . . . Contrary to the Examiner's interpretation, Fields does not teach that a part of the binding space is identical to a part of the amplification space.

(App. Br. 12.) We agree.

Claims 37, 38 , 69, and 70 depend directly or indirectly on claim 36.

Accordingly, we reverse the rejection of claims 36-38, 69, and 70 under 35 U.S.C. § 102(e) as being anticipated by Fields.

Claim 72:

Claim 72 is drawn to an apparatus comprising a capillary reaction vessel surrounded by a heatable metal layer.

According to the Examiner "Fields teaches that the apparatus comprises a space for binding nucleic acids . . .; reagents for amplifying and detecting nucleic acids bound to the surface . . .; and a sample transport

mechanism which transports the sample and reagent. . . ." (Ans. 9). The Examiner did not identify, and we do not find, a teaching in Fields of an apparatus comprising, *inter alia*, a capillary reaction vessel surrounded by a heatable metal layer as is required by claim 72 (*see also* App. Br. 13). Claims 73 and 76 depend from claim 72. Accordingly, we reverse the rejection of claims 72, 73, and 76 under 35 U.S.C. § 102(e) as being anticipated by Fields.

CONCLUSION

In summary, we reverse the rejections of record.

REVERSED

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